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BIOMET INC

SEP 20 2007

510(k) Summary

Preparation Date: June 29, 2007

Applicant/Sponsor: Biomet Sports Medicine (Formerly known as Arthrotek, Inc.)

Contact Person: Elizabeth Wray

Proprietary Name: Harpoon® Suture Anchor

Common Name: Suture Anchor

Classification Name:
- MBI (888.3040): Fastener, fixation, nondegradable, soft tissue
- HWC (888.3040): Screw, fixation bone

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Device	Harpoon® Suture Anchor	BioRaptor™	Metal Screw Anchor (Currently Ti Screw)
Manufacturer	Biomet Sports Medicine	Smith & Nephew	Biomet Sports Medicine
510(k) Number	K973775	K053344	K012503

Device Description: The Harpoon® Suture Anchor is comprised of either stainless steel or titanium material designed with a collar that provides resistance to pullout of the device. It is preloaded with a polyethylene suture and available in two sizes.

Indications for Use/Intended Use:
Harpoon® and Mini-Harpoon® Suture Anchors are indicated for use in soft tissue reattachment procedures. Specific Indications are:

Shoulder - Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair, and anterior shoulder instability repair

Wrist – Scapholunate ligament reconstruction

Elbow – Biceps tendon reattachment, Ulnar or radial collateral ligament reconstruction, and lateral epicondylitis repair

Knee – Extracapsular Repair (Medial collateral ligament repair, lateral collateral ligament repair, and posterior oblique ligament repair), joint capsule closure, iliotibial band tenodesis reconstruction, patellar realignment and tendon repair, and vastus medialis obliquus (VMO) muscle advancement

Foot and Ankle - Hallux valgus repairs, medial or lateral instability repair/reconstruction, Achilles tendon repair/reconstruction, midfoot reconstruction, and metatarsal ligament/tendon repair/reconstruction

Hip – Capsular Repair (acetabular labral repair)

Summary of Technologies: The technological characteristics (materials, design, sizing, and indications) of the Harpoon® Suture Anchor are similar or identical to the predicate device or other previously cleared devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2007

Biomet Sports Medicine, Inc.
% Ms. Elizabeth Wray
Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K071816
Trade/Device Name: Harpoon® Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR, MBI
Dated: June 29, 2007
Received: July 2, 2007

Dear Ms. Wray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or 240-276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071816

Device Name: Harpoon® Suture Anchor

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Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071816